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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,253	02/20/2002	Raz Jelinek	501116.20506	2898

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EXAMINER	
GANGLE, BRIAN J	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,253	JELINEK, RAZ	
	Examiner	Art Unit	
	Brian J. Gangle	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *11-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-13 are pending. Claims 11-13 are withdrawn as being drawn to a nonelected invention. Claims 1-10 are currently under examination.

Election/Restrictions

Applicant's election with traverse of Group I in the response filed 7/7/2005 is acknowledged. The traversal is on the ground(s) that the claims, as amended, comprise one invention with two embodiments, and that all of the methods contain at least one special technical feature in common. This is not found persuasive for the reasons set forth below.

The claims, as amended, are still drawn to same separate inventions. Further, a special technical feature, as defined by PCT Rule 13.2, is required to define a contribution over the art. Charych (PCT Publication WO 98/39632, 1998) anticipates the technical feature of Group I. Therefore, there is no special technical feature linking the inventions of groups I-III.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is

(a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 10 recites the broad recitation "phospholipids", and the claim also recites "sphingolipids" which is the narrower statement of the range/limitation. In addition, claim 10 recites the broad recitation "sphingolipids", and the claim also recites "ceramides" which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6, and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Charych et al. (PCT Publication WO 97/27316, 7/1997).

The instant claims are drawn to methods for detecting the presence of an analyte in a sample, said analyte being chemically non-reactive with lipids or with a polymer having an absorption band which may be shifted from a first wavelength in the visible region to a second wavelength in the visible region, which comprises:

a) providing a polymeric matrix comprising said lipids and said polymer;

b) introducing into said sample or into said polymeric matrix means enabling said analyte to cause a non-chemical change accompanied by a color transition in said polymeric matrix; and

c) contacting the sample with the polymeric matrix and observing a color transition of the matrix, indicating the presence of the analyte (claim 1).

Said method is further limited to where the analyte is a biological ligand and the means allowing said ligand to cause a non-chemical change in the polymeric matrix are provided by a receptor having the capability to bind said ligand, said receptor being linked to a spacer arm

located within the lipid domain of said matrix (claim 4); where the analyte is a peptide (claim 6), specifically, a membrane protein (claim 8); and where the polymer is polydiacetylene obtained by polymerization of a monomer selected from the group consisting of tricosadiynoic acid, tricosadiynoic methyl esters, pentacosadiynoic acid, and pentacosadiynoic methyl esters (claim 9).

Charych et al. disclose a method of detecting an analyte (influenza virus) where a mixture of a sialoside lipid and polydiacetylene was polymerized to form a film. A tetraethylene glycol spacer serves to extend the carbohydrate ligand that serves as a receptor that binds to the hemaglutinin of the influenza virus (a membrane protein) beyond the matrix. A sample containing influenza virus was contacted with the polymeric matrix and binding of the sialicid acid resulted in a color change in the polydiacetylene polymer from blue to red (see page 30, lines 7-14 and lines 30-37). Regarding claim 9, the products of the prior art reference appear to be the same or an obvious variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. a polydiacetylene polymer. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972).

Claims 1, 4, 6, and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Charych et al. (Science, 261:585-588, 1993).

The instant claims are drawn to methods for detecting the presence of an analyte in a sample, said analyte being chemically non-reactive with lipids or with a polymer having an absorption band which may be shifted from a first wavelength in the visible region to a second wavelength in the visible region, which comprises:

a) providing a polymeric matrix comprising said lipids and said polymer;

b) introducing into said sample or into said polymeric matrix means enabling said analyte to cause a non-chemical change accompanied by a color transition in said polymeric matrix; and

c) contacting the sample with the polymeric matrix and observing a color transition of the matrix, indicating the presence of the analyte (claim 1).

Said method is further limited to where the analyte is a biological ligand and the means allowing said ligand to cause a non-chemical change in the polymeric matrix are provided by a receptor having the capability to bind said ligand, said receptor being linked to a spacer arm located within the lipid domain of said matrix (claim 4); where the analyte is a peptide (claim 6), specifically, a membrane protein (claim 8); and where the polymer is polydiacetylene obtained by polymerization of a monomer selected from the group consisting of tricosadiynoic acid, tricosadiynoic methyl esters, pentacosadiynoic acid, and pentacosadiynoic methyl esters (claim 9).

Charych et al. disclose a method of detecting an analyte (influenza virus) where a mixture of a sialoside lipid and polydiacetylene was polymerized to form a film. A tetraethylene glycol spacer serves to extend the carbohydrate ligand that serves as a receptor that binds to the hemaglutinin of the influenza virus (a membrane protein) beyond the matrix. A sample containing influenza virus was contacted with the polymeric matrix and binding of the sialicid acid resulted in a color change in the polydiacetylene polymer from blue to red (see page 585, abstract). Regarding claim 9, the products of the prior art reference appear to be the same or an obvious variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. a polydiacetylene polymer. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972).

Claims 1 and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Charych (PCT Publication WO 98/39632, 9/1998).

The instant claims are drawn to methods for detecting the presence of an analyte in a sample, said analyte being chemically non-reactive with lipids or with a polymer having an

absorption band which may be shifted from a first wavelength in the visible region to a second wavelength in the visible region, which comprises:

a) providing a polymeric matrix comprising said lipids and said polymer;

b) introducing into said sample or into said polymeric matrix means enabling said analyte to cause a non-chemical change accompanied by a color transition in said polymeric matrix; and

c) contacting the sample with the polymeric matrix and observing a color transition of the matrix, indicating the presence of the analyte (claim 1).

Said method is further limited to where the analyte is a biological ligand and the means allowing said ligand to cause a non-chemical change in the polymeric matrix are provided by a receptor having the capability to bind said ligand, said receptor being linked to a spacer arm located within the lipid domain of said matrix (claim 4); where the biological ligand is selected from the group consisting of antibodies, antigens and epitopes, and the spacer arm is a peptide or one or more alkyl chains (claim 5); where the analyte is a peptide (claim 6), specifically a short membrane peptide containing no more than 50 amino acids (claim 7) or a membrane protein (claim 8); where the polymer is polydiacetylene obtained by polymerization of a monomer selected from the group consisting of tricosadiynoic acid, tricosadiynoic methyl esters, pentacosadiynoic acid, and pentacosadiynoic methyl esters (claim 9); and where the lipids are selected from the group consisting of phospholipids, sphingolipids, and ceramides (claim 10).

Charych discloses a method for detecting the presence of an analyte through the detection of color changes in biopolymeric materials that result from conformational changes in the biopolymeric material (see page 21, lines 21-25). The biopolymeric material is disclosed as polydiacetylene (see page 26, lines 1-3), and can be mixed with a "dopant" such as ceramide (see page 4, lines 10-16). The biopolymeric materials of Charych also include a ligand which serves as a receptor for detecting the analyte of interest and binding of the analyte to the ligand results in a disruption of the polymer backbone of the biopolymeric material, resulting in a color change (see page 37, lines 15-21). The method can be used to detect a large variety of analytes (ligands of the instant invention), including antibodies, antigens, membrane receptors, microorganisms, membrane fragments, and enzymes (see page 9, lines 30-33, and page 41, lines 7-10). The ligand (i.e. the receptor of the instant invention) is chosen to bind to the analyte of choice, and can be an antibody, peptide, chelating compound, or other of a broad range of ligands (p. 38,

lines 4-19). Regarding claim 5, the antibodies used as ligands by Charych are membrane proteins that comprise a receptor portion and a heavy chain that serves as a spacer arm (see page 9, lines 4-6). Regarding claim 7, membrane fragments would necessarily include short membrane peptides, thus Charych anticipates this limitation of the claim. Regarding claim 9, the products of the prior art reference appear to be the same or an obvious variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. a polydiacetylene polymer. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charych (PCT Publication WO 98/39632, 9/1998) in view of Suzuki et al. (Anal. Chem., 61:382-384, 1989).

The instant claims are drawn to methods for detecting the presence of an analyte in a sample, said analyte being chemically non-reactive with lipids or with a polymer having an absorption band which may be shifted from a first wavelength in the visible region to a second wavelength in the visible region, which comprises:

a) providing a polymeric matrix comprising said lipids and said polymer;

b) introducing into said sample or into said polymeric matrix means enabling said analyte to cause a non-chemical change accompanied by a color transition in said polymeric matrix; and

c) contacting the sample with the polymeric matrix and observing a color transition of the matrix, indicating the presence of the analyte (claim 1).

Said method is further limited to where the analyte is an ion (specifically a metal cation in claim 3) and where the means allowing said ion to cause a non-chemical change in the polymeric matrix are ionophores (claim 2); where the analyte is a biological ligand and the means allowing said ligand to cause a non-chemical change in the polymeric matrix are provided by a receptor having the capability to bind said ligand, said receptor being linked to a spacer arm located within the lipid domain of said matrix (claim 4); where the biological ligand is selected from the group consisting of antibodies, antigens and epitopes, and the spacer arm is a peptide or one or more alkyl chains (claim 5); where the analyte is a peptide (claim 6), specifically a short membrane peptide containing no more than 50 amino acids (claim 7) or a membrane protein (claim 8); where the polymer is polydiacetylene obtained by polymerization of a monomer selected from the group consisting of tricosadiynoic acid, tricosadiynoic methyl esters, pentacosadiynoic acid, and pentacosadiynoic methyl esters (claim 9); and where the lipids are selected from the group consisting of phospholipids, sphingolipids, and ceramides (claim 10).

Charych discloses a method for detecting the presence of an analyte through the detection of color changes in biopolymeric materials that result from conformational changes in the biopolymeric material (see page 21, lines 21-25). The biopolymeric material is disclosed as polydiacetylene (see page 26, lines 1-3), and can be mixed with a "dopant" such as ceramide (see page 4, lines 10-16). The biopolymeric materials of Charych also include a ligand which serves as a receptor for detecting the analyte of interest and binding of the analyte to the ligand results in a disruption of the polymer backbone of the biopolymeric material, resulting in a color change (see page 37, lines 15-21). The method can be used to detect a large variety of analytes (ligands of the instant invention), including ions, antibodies, antigens, membrane receptors, microorganisms, membrane fragments, and enzymes (see page 9, lines 30-33, and page 41, lines 7-10). The ligand (i.e. the receptor of the instant invention) is chosen to bind to the analyte of choice, and can be an antibody, peptide, chelating compound, chromophores, or other of a broad range of ligands (p. 38, lines 4-19). Regarding claim 5, the antibodies used as ligands by

Charych are membrane proteins that comprise a receptor portion and a heavy chain that serves as a spacer arm (see page 9, lines 4-6). Regarding claim 7, membrane fragments would necessarily include short membrane peptides, thus Charych anticipates this limitation of the claim. Regarding claim 9, the products of the prior art reference appear to be the same or an obvious variant of the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. a polydiacetylene polymer. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972).

Charych differs from the instant invention in that ions, specifically, metal cations, are not disclosed as the analyte and ionophores are not disclosed as the means to detect said cations.

Suzuki et al. discloses that the ionophore A23187 is useful as an optical sensor for Mg and Ca cations (see page 382, column 1, paragraph 3). Suzuki et al. discloses that using the ionophore A23187 as an optical sensor is advantageous because it is insoluble in water and because cation-ionophore complex formation and decomposition can be controlled reversibly according to the pH of the aqueous solution contacting the molecule (see page 382, column 1, paragraph 3).

Consequently, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the ionophore A23187 as a detection means in the colorimetric detection method of Charych in order to take advantage of the fact that ionophore A23187 is insoluble in water and because cation-ionophore complex formation and decomposition can be controlled reversibly according to the pH of the aqueous solution contacting the molecule.

One would have had a reasonable expectation of success because Charych discloses that their method can be used to detect ions and the ligands used in said method can include, among other things, chromophores and chelating compounds.

Conclusion

No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Gangle whose telephone number is 571-272-1181. The examiner can normally be reached on M-F 8:00 am - 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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